

REMARKS

In the Office Action, the Examiner rejected claims 64, 66, 67, and 83 under 35 U.S.C § 102(b) as being anticipated by U.S. Patent No. 5,702,343 to Alferness, and objected to claims 59-62, 68, and 84.

Of the pending claims, claim 83 is the sole independent claim. Claim 83 is directed to a method of treating an in situ mitral valve and recites

positioning a passive device with respect to a heart such that, throughout the cardiac cycle, a portion of the device contacts and passively alters a geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus associated with the in situ mitral valve, wherein the passive device draws together leaflets of the in situ valve to promote closure of the in situ valve.

Alferness discloses a cardiac reinforcement device and a method for treating cardiomyopathy. More specifically, Alferness discloses a device and treatment method that provide reinforcement of the cardiac wall during diastole by applying the device to the epicardial surface of the heart. See, e.g., Alferness col. 1, lines 8-14. Alferness specifically teaches that the disclosed cardiac reinforcement devices do not provide cardiac assistance during systole, in contrast to prior art ventricular assistance devices. See, e.g., Alferness, col. 3, lines 1-5 and 33-38. Alferness further teaches that the cardiac reinforcement devices function so as to reduce cardiac dilation and thereby potentially prevent or reduce problems that are associated with such dilation. See, e.g., Alferness, col. 1, lines 25-30 and col. 5, lines 26-44. Thus, contrary to the Examiner's assertions otherwise in the Office Action, Alferness neither discloses nor suggests, either explicitly or otherwise, that "throughout the cardiac cycle, a portion of the device contacts and passively alters a geometry of heart structure" or that "the passive device

draws together leaflets of the in situ valve to promote closure of the in situ valve,” as recited in independent claim 83.

In the Office Action, the Examiner asserts that column 1, lines 25-30 and column 5, lines 26-44 of Alferness allegedly teach that the cardiac reinforcement device of Alferness draws together leaflets of the *in situ* valve to promote closure of said valve. See Office Action at page 2. However, the cited passages, as well as the remainder of the disclosure in Alferness, describe a device that constrains cardiac expansion during diastole so as to prevent enlargement (*i.e.*, dilation) of the heart. These passages do not disclose or otherwise suggest a device that acts on the valve or closes the valve. At most, Alferness teaches that the use of the cardiac reinforcement devices for constraining cardiac expansion and preventing cardiac dilation may have a side effect of reducing valvular leakage. However, this is not a teaching of a device that “draws together leaflets of the *in situ* valve to promote closure of said valve.”

As further alleged support for the Section 102 rejection based on Alferness, the Examiner asserts that the teaching of Alferness to position a cardiac reinforcement jacket device under the parietal pericardium is a teaching of

[altering] the geometry of the cardiac wall throughout the cardiac cycle by virtue of the device thickness shifting the cardiac wall inwardly from the parietal pericardium and the device material (and thickness) altering the dynamic response characteristics of the cardiac wall, the device, and the parietal pericardium in combination.

See Office Action at page 2.

Alferness does not explicitly disclose altering the geometry of the cardiac wall throughout the cardiac cycle. To the contrary, as discussed above, Alferness explicitly teaches that the disclosed cardiac reinforcement devices act during diastole and not

during systole to provide cardiac reinforcement. Since Alferness contains no explicit disclosure that the cardiac reinforcement devices alter the geometry of the cardiac wall throughout the cardiac cycle, it appears the Examiner may be relying on inherency principles to support the rejection based on Alferness. To establish inherency, the Examiner must show that "the missing descriptive matter is *necessarily* present" in the reference. See M.P.E.P. § 2112, Original Eighth Ed., Aug. 2001, Revision May 2004 (*quoting In re Robertson*, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112 (emphasis in original.)

In the present case, the Examiner has not established that Alferness's disclosure of placing a cardiac reinforcement jacket under the parietal pericardium is necessarily a teaching of altering a geometry of heart structure throughout the cardiac cycle, as required by claim 83. This is especially true in light of Alferness's explicit disclosure that the devices act during diastole and not during systole. For such altering of heart structure geometry through the cardiac cycle to occur, the cardiac reinforcement device would need a thickness sufficient to occupy enough space between the heart and the parietal pericardium. However, a cardiac reinforcement device could have a thickness whereby the device does **not** occupy sufficient space between the parietal pericardium and the cardiac wall so as to shift the cardiac wall inwardly or otherwise alter heart structure geometry throughout the cardiac cycle. In this regard, Alferness contains no explicit disclosure regarding the thickness of the device. Since a device without

sufficient thickness to occupy the appropriate space may exist, the Examiner has failed to establish inherency.

Notably, the Examiner has provided no evidence to support the assertion that the cardiac reinforcement devices disclosed by Alferness necessarily have the thickness required to perform the alleged functions, and instead relies on conclusory assertions. If the Examiner maintains the rejection based on Alferness, Applicants request that the Examiner supply documentary evidence supporting the assertions regarding the thickness of the cardiac reinforcement devices and that they necessarily act throughout the cardiac cycle. For example, Applicants request that the Examiner supply either a reference or a personal affidavit setting forth specific facts within his personal knowledge, in accordance with 37 C.F.R. § 1.104(d)(2) and M.P.E.P. § 2144.03.

Moreover, it is likely that it would be undesirable for the cardiac reinforcement devices disclosed by Alferness to have a thickness large enough to occupy sufficient space between the heart and the parietal pericardium because this could cause the device to compress the heart in a uniform manner throughout the cardiac cycle. Such uniform compression could result in tamponade of the heart muscle, which is an undesirable compression of the heart typically caused by blood or fluid accumulation in the space between the myocardium and the pericardium.

For at least the above reasons, therefore, Alferness fails to disclose or otherwise suggest, either explicitly or otherwise, a method for treating an *in situ* mitral valve, as recited in claim 83, and the Section 102 rejection based on Alferness should be withdrawn.

Claims 59-62, 64, 66-68, and 84 depend from claim 83 and are therefore allowable for at least the same reasons claim 83 is allowable. In addition, at least some of those dependent claims recite unique features and combinations that are neither taught nor suggested by the cited art and thus at least some are also separately patentable.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Please grant any extensions of time required to enter this request for reconsideration and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: *Susanne T. Jones*
Susanne T. Jones
Reg. No. 44,472